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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/621,593	07/21/2000	Nanda de Groot	4497US	4769

7590 07/16/2002
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EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/621,593	Applicant(s) DE GROOT ET AL.	
	Examiner Brian Whiteman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 26-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 26-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>15</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Non-Final Rejection

Claims 1 and 26-36 are pending examination.

Applicant's traversal, copies of a sequence listing on paper and disk, the amendments to the specification, cancellation of claims 3-14, 17-19, 22-25, addition of claims 26-36, and amendment to claim 1 in paper no. 14 filed on 4/24/02 is acknowledged and considered.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

It is noted that Applicant is preparing an IDS to ensure that all the references are considered. See page 8.

NOTE: To help save time and avoid duplication of an article already listed, applicant should review the references already cited by the examiner on the PTO-892.

Drawings

NOTE: In the next response, please submit a response to the PTO 498 because a PTO 498 was filed with the non-final rejection dated 10/21/01, paper no. 11, and the applicant has not submitted proposed corrections to the drawings or corrected drawings. If the reply to the Final

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Rejection does not have a response to the 498, the response will be considered **non-responsive**.

See 37 CFR 1.85(a).

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because of the word "means". Correction is required. See MPEP § 608.01(b).

Claim Objections

The objection for claims 7 and 22 is moot in view of the cancellation of claims 7 and 22.

The rejection for claims 1, 3-14, 17-19 and 22-25 under 112 written description is moot in view of the cancellation of claims 3-14, 17-19, 22-25, addition of claims 26-36, and amendment to claim 1 in paper no. 14. However, in view of the addition of new claims, a new rejection under 112, new matter, follows for claims 26, 27, 32, and 34:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26-27, 32, and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claims 26-27, 32, and 34 filed on 4/24/02 introduce new subject matter into the disclosure. The application and the originally filed claims as a whole are directed to: A non-human animal wherein a cell of said animal comprises a recombinant nucleic acid encoding a protein capable of transporting an immunoglobulin from the cell's basolateral side to the cell's apical side.

Amended claim 27 for example, recites: A transgenic farm animal having a genome, the genome comprising a recombinant nucleic acid encoding a polymeric immunoglobulin receptor (pIgR) protein, wherein said protein is capable of transporting an immunoglobulin protein across the basolateral side of an epithelial cell's apical side, resulting in over-expression of the immunoglobulin protein on the epithelial cell's apical side in comparison to another immunoglobulin protein located on the epithelial cell's basolateral side, wherein the immunoglobulin protein is selected from the group consisting of IgM, IgA, IgG1, and IgG2.

The full scope of the claimed invention as newly amended is directed to over-expressing an immunoglobulin protein selected from the group consisting of IgM, IgA, IgG1, and IgG2 on the basolateral side of a transgenic farm animal. However, the as-filed specification as a whole neither teaches nor suggests nor contemplates using an immunoglobulin protein from the group consisting of IgG1 and IgG2. In fact, the paragraph cited by applicant for support of the newly

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added claim clearly indicates that applicant's claims are directed to A transgenic farm animal having a genome, the genome comprising a recombinant nucleic acid encoding a polymeric immunoglobulin receptor (pIgR) protein, wherein said protein is capable of transporting an immunoglobulin protein across the basolateral side of an epithelial cell's apical side, resulting in over-expression of the immunoglobulin protein on the epithelial cell's apical side in comparison to another immunoglobulin protein located on the epithelial cell's basolateral side, wherein the immunoglobulin protein is selected from the group consisting of IgM or IgA. More specifically page 6, lines 21-25 of the present specification, states:

“A protein capable of transporting a member of the first class of immunoglobulin from the basolateral side to the apical side can be any receptor over expressed via for instance transgenesis or via other means, and able to transport Ig's of any kind across epithelial cells. A non-limiting example of such a protein is an IgG1 receptor.”

It is apparent from the as-filed specification and the cited paragraph on pages, that applicant at the time the invention was made did not intend or contemplate using an immunoglobulin protein from the group consisting of IgG1 and IgG2 because they are not proteins but receptors used for transporting the desired proteins. Thus, one skilled in the art on the basis of applicant's specification at the time the invention was made would not envision over-expressing an immunoglobulin protein from the group consisting of IgG1 and IgG2. Thus, there is no evidence that the applicant was in possession of the full scope of the invention of the base claims and claims dependent thereof, as it is now claimed, at the time the application was filed.

Applicants' traversal is not found persuasive because it is not applicable to the rejection under 112, new matter, set forth above.

It is noted that in an interview with applicant's representative, Brett Crockett, applicant indicated that he would remove the limitation encompassing IgG1 and IgG2 from the claims and file an amendment displaying this change, see paper no. 15. However, an amendment with this change is not of record. Therefore, the rejection remains.

The rejection for claims 1, 3-14, 17-19 and 22-25 under 112, enablement, is moot in view of the amendment to claim 1, cancellation of claims 3-14, 17-19, 22-25, and the addition of claims 26-36.

The claims rejected under 112 second are moot in view of the amended claims.

Claim Rejections - 35 USC § 102

The rejection under 102(b) is moot in view of the new claims and evidence provided by the applicant that the article used was in fact a 102(a) instead of a 102(b). See page 6. However, in view of the amended claims, a new rejection under 102(a) follows:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 26-36 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by DeGroot et al. (Transgenic Research, Vol. 8, pages 125-135). DeGroot generated four different transgenic mice lines over-expressing the murine pIgR gene at 10-30 fold increased mRNA levels, relative to the endogenous mRNA levels in their mammary glands (page 126). The

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transgene (pIgR) was expressed in the mammary gland in a tissue specific manner and only during lactation (page 126). The secretory component (SC) protein levels in the milk of the four transgenic lines were increased 10-270 fold compared to endogenous SC protein levels (page 126).

Applicant traverses that a declaration from Herman Albert de Boer evidencing this data and identifying the material as Applicant's own work will be submitted to the office. See page 6.

Applicant's traversal is acknowledged and is not found persuasive because a Declaration by the applicant has not been submitted to overcome the 102(a) rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, primary examiner, Dave Nguyen can be reached at (703) 305-2024.

If attempts to reach the primary examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.


Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635
7/9/02



DAVE T. NGUYEN
PRIMARY EXAMINER